

REMARKS/ARGUMENTS

Reconsideration of the captioned application as amended herewith is respectfully requested.

This response is being filed concurrently with a **Petition for a One (1) Month Extension of Time**, which would extend the period of response from 15 February 2008 to 15 March 2008.

The Office Action:

- a) Withdrew claims 7 – 10 and 12 from further consideration;
- b) Objected to claims 2- 6, 11, and 13 - 22 for allegedly bring in improper form;
- c) Rejected claims 1 - 3 under 35 USC §112, first paragraph, as allegedly failing to comply with the written description requirement;
- d) Rejected claims 1 - 3 under 35 USC §102(b) as being allegedly anticipated by WO 96/40829 to Sojomihardjo et al. (“Sojomihardjo”); and
- e) Provisionally rejected claims 1 – 3 on the ground of nonstatutory obviousness-type double patenting over copending U.S. Patent Application Nos. 10/554,375; 10/529,156; 10/497,442; and 10/579,897.

New claim 23 was added. Support for the subject matter in this claim may be found in, for example, claims 1, 17, and 20 as originally filed, and as such does not introduce new matter into the application. Claims 7 – 10 and 12 were withdrawn in the Office Action, claims 1, 20, and 21 were cancelled, and claims 1 – 6, 11, and 13 – 16, 18, 19, 22, and 23 remain pending in this application after entry of this Response.

Claim 1 was clarified to include that the wound dressing is comprised of a “donor layer comprised of a therapeutic agent... wherein the barrier layer initially separates the donor layer in the wound dressing from wound fluid when in use.” Support for this language may be found in the Specification as originally filed at, for example, page 11, lines 1 - 21, and as such does not introduce new matter into the Specification. Applicants’ amendment herein is not a concession or admission that original claim 1 is unpatentable. Applicants reserve the right to prosecute the subject matter of original claim 1 in a continuing application.

Claims 2 and 3 stand “objected to under 37 CFR 1.75(c) as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim.” Applicants respectfully disagree. Claim 2 is directed to a wound dressing “wherein the protease is associated with wound infection or ulcer formation.” When claim 2 is read in view of independent

claim 1, it is evident that claim 2 further defines the “cross-linkages comprise[d] of oligopeptidic sequences.” More specifically, the wound dressing of claim 2 is directed to a certain sub-group of cross-linkages i.e., those that are “comprise[d] of oligopeptidic sequences which are cleavable by a [certain kind of] protease,” i.e., those proteases that are “associated with wound infection or ulcer formation” as set forth in claim 2. Similarly, when claim 3 is read in view of independent claim 1, it is evident that claim 3 further defines the polymers of claim 1. More specifically, the wound dressing of claim 3 is directed to a certain sub-group of polymers, i.e., those that “are not degraded by the protease or other factors that may be present in the wound environment.” In view of these arguments, as well as the amendments made to remove the multiple dependencies in claims 3, 4, 6, 11, 13, 14, 19, and 22, Applicants respectfully submit that the objection of claims 2 – 6, 11, and 13 – 22 under 37 CFR 1.75(c) has been overcome and should be withdrawn.

I. The Rejection of Claims 1 - 3 Under 35 USC §112, First Paragraph, Should Be Withdrawn

Claims 1 - 3 stand “rejected under 35 USC 112, first paragraph, as [allegedly] failing to comply with the written description requirement.” Applicants respectfully disagree.

According to the Office Action,

The oligopeptide sequences [of claim 1] are described as being cleavable by a protease... One of skill in the art would not recognize that the applicant was in possession of wound dressings with oligopeptide sequences of the scope of the genus of claim 1.”

In this rejection, the Office Action cited several “proteases such as trypsin, pepsin thrombin, and papain that would cleave an oligopeptide sequence,” then alleged that there could “be at least ... over 2 billion... possible peptides.” “Even though approximately 30 different oligopeptide sequences are recited in the specification,” the Office Action concluded that “the recited peptides [allegedly] do not represent the genus (emphasis added).

Applicants respectfully point out that claim 1 is not directed to all proteases, but rather is directed to a particular genus of proteases, i.e., “protease[s] associated with wound fluid such that the rate of release of the therapeutic agent increases in the presence of [those] protease[s].” In fact, the Office Action has failed to show that the cited “trypsin, pepsin thrombin, and papain” proteases are associated with wound fluid.

Therefore, because the scope of claim 1 is not directed to all oligopeptidic sequences or all proteases, but rather just a particular genus of oligopeptidic sequences that are cleavable by a particular genus of proteases, i.e., “protease[s] associated with wound fluid such that the rate of release of the therapeutic agent increases in the presence of [those] protease[s],” Applicants respectfully submit that the specification contains a sufficient written description of the invention “that would reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” Therefore, Applicants

respectfully submit that the rejection of claims 1 – 3 under 35 USC 112, first paragraph, has been overcome and should be withdrawn.

II. The Rejection of Claims 1 - 3 Under 35 USC §102(b) Over Sojomihardjo Should Be Withdrawn

Claims 1 - 3 stand rejected under 35 USC §102(b) as allegedly being anticipated by Sojomihardjo. Applicants respectfully disagree for the reasons that follow.

Rejections under 35 USC §102 are proper only when the claimed subject matter is identically disclosed or described in the prior art. In re Marshall, 198 USPQ 344 (CCPA 1978). In other words, to constitute an anticipation, all material elements recited in a claim must be found in one unit of prior art. Id. The exclusion of a claimed element from a prior art reference is enough to negate anticipation under 35 USC §102 by that reference. Atlas Powder Co. v. E.I. Du Pont de Nemours & Co., 224 USPQ 409 (Fed. Cir. 1984). Applicants respectfully submit that Sojomihardjo does not anticipate Applicants' currently amended claims 1 through 3 because Sojomihardjo does not describe all the elements contained therein.

According to the Office Action, Sojomihardjo discloses polymers "having a biologically active material (i.e. therapeutic agent) entrapped therein. As set forth on page 17, lines 26 – 30 of Sojomihardjo, the "polypeptides described herein [can] be employed to entrap biologically active material therein, in addition, the polypeptide employed for encapsulation can itself impart physiological activity to the resulting article."

By contrast, claim 1 as presently clarified is directed to a "wound dressing comprising: (a) a donor layer comprised of a therapeutic agent; and (b) a barrier layer, ... wherein the barrier layer initially separates the donor layer in the wound dressing from wound fluid when in use. " The Office Action has failed to show where Sojomihardjo discloses or suggests the use of a "donor layer" comprised of a therapeutic agent as claimed herein.

Therefore, because Sojomihardjo, fails to disclose or suggest at least one element of Applicants' independent claim 1, i.e., e.g., a "donor layer comprised of a therapeutic agent" (emphasis added), Applicants respectfully submit that the rejection of claim 1 under 35 USC §102(b)) has been overcome and should be withdrawn. Applicants further respectfully submit that the rejection of claims 2 - 3, which are dependent upon claim 1 and thus incorporate all of the limitations therein, under 35 USC §102(b) has been overcome and should similarly be withdrawn.

The Obvious Double Patenting Rejections Are Moot

At the current time, Applicants believe that the obviousness-type double patenting rejection is moot as the subject matter of co-pending United States Application Serial Nos.: 10,554,375; 10/529,156; 10/497,442; and 10/579,897 has not issued into a granted patent.

Applicants wish to point out that the issue fee for United States Application No. 10/554,375 has been paid. According to the Office Action, the obviousness-double patenting rejection was based upon claims 1 – 4, and 7 – 17 of the “10/27/07 claim set... of copending Application No. 10/554,375.” Applicants further wish to point out that claims in United States Application No. 10/554,375 were subsequently subject to an Examiner’s Amendment on 3 December 2007, in which (a) claim 1 was amended; (b) claims 2-4, 7, and 17 were cancelled; and (c) claims 1 and 8 – 16 were allowed.

Conclusion

It is submitted that the foregoing amendments and remarks place the case in condition for allowance. A notice to that effect is earnestly solicited.

In the event that all of the claims are not in condition for allowance, Applicants respectfully request for an interview with the Examiner before the preparation of the next Office Action.

Respectfully submitted,

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Att:
(1) Petition for One (1) Month Extension of Time